PR 35 (73FR45635)

Rulemaking Comments

From:Wallace, Steven A [Steven.Wallace2@providence.org]Sent:Monday, October 20, 2008 7:02 PMTo:Rulemaking CommentsCc:Halligan, John; Galloway, Christopher G; Ning, Yongli; Katinszky, Wanda; Lamoureux, BruceSubject:RIN 3150-Al26

Hello NRC Rulemaking,

I wish to comment on the Medical Use of Byproduct Material – Amendments / Medical Event Definitions RIN 3150-Al26

Re: Incorporating Microsphere treatment into the category of permanent implant brachytherapy (as per page 45636 of Federal Register Vol 73, No. 152).

Per the proposed rule 35.3045 Report and notification of a medical event (2) (i) The total source strength implanted in the treatment site differing from the preimplantation written directive by 20 percent or more.

I feel that for Microsphere treatment of liver metastasis, this rule will result in the definition of a large number of Medical Events when in fact the variations are due to clinical necessity at the time of procedure.

Your consideration would be greatly appreciated,

Regards,

Steven Wallace

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